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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/829,168
Applicant(s)	:	Allan J. Lepine
Filed	:	April 9, 2001
Title	:	METHOD OF ADMINISTERING A MILK SUBSTITUTE TO CRITICAL CARE ANIMALS
TC/A.U.	:	1761
Examiner	:	Arthur L. Corbin
Conf. No.	:	1328
Docket No.	:	P-116RC
Customer No.	:	27,752

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This Brief is filed in support of the appeal for the above-captioned patent application. A timely Notice of Appeal was filed on May 19, 2004. Attached hereto is a Petition for Extension of Time under 37 CFR 1.17(a)(5), making this Brief due December 19, 2004. As December 19, 2004 falls on a Sunday, this Brief may be timely filed on December 20, 2004.

REAL PARTY IN INTEREST

The real party in interest is The Iams Company, an affiliate of The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

A Decision on Appeal by the Board of Patent Appeals and Interferences was made in related, co-pending U.S. Patent Application Serial No. 09/163,778, to which the present patent application claims priority. A copy of this Decision is attached herewith in the "Related Proceedings Appendix."

STATUS OF CLAIMS

Claims 1 and 3 – 12 have been finally rejected.

Claims 1 and 3 – 12 are appealed. A complete copy of the appealed claims is set forth in the "Claims Appendix" attached herewith.

STATUS OF AMENDMENTS

There were no amendments filed subsequent to the Notice of Appeal.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a method for providing nutrition to a critical care canine. Critical care animals are usually under extreme stress and may be in shock due to extensive trauma, systemic disease, cancer, chemotherapy, malnutrition or ingestion of toxins. Responsible conditions may have acute onset as in the case of wounds, but may also be brought on by more chronic conditions such as malnutrition, neglect, or end stages of chronic disease such as parasitic disease, hepatic, respiratory, or cardiac disease. Diseases resulting in critical care situations may be the result of metabolic dysfunction or infections such as fungal, viral, bacterial or parasitic infections. *See* specification page 1, lines 17 – 25.

Because of the stress these animals are under, the animals tend to have higher energy requirements relative to healthy animals and are often susceptible to malnutrition. Accordingly, provision of proper energy and other nutrients, such as through a substitute for natural canine milk, is an important advance in the management of the critical care animal. *See* specification page 1, line 26 to page 2, line 2.

As has been stated in the present specification, commercial canine milk replacers have been previously formulated based upon limited research data. Rather, but for the inventor's independent research leading to the present invention, the contents of such milk may have still been unknown; the present specification details the discovered composition of such milk, thereby advancing the capability for technical progress in the area of critical animal care.

The present invention is directed to a method for administering to a canine an amount of an artificially produced canine milk substitute composition. The artificially produced canine milk substitute composition comprises, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates; wherein said protein comprises casein and whey in a weight ratio of about 70:30.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

GROUND 1.

Claims 1 and 3 – 5 have been finally rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as having been obvious in view of the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778.

GROUND 2.

Claims 7 – 9, 11 and 12 have been finally rejected under 35 U.S.C. § 103(a) as having been obvious in view of the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778.

GROUND 3.

Claim 6 has been finally rejected under 35 U.S.C. § 103(a) as having been obvious over the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778, further in view of Gil *et al.*, U.S. Patent No. 5,709,888 (herein referenced as "Gil").

GROUND 4.

Claim 10 has been finally rejected under 35 U.S.C. § 103(a) as having been obvious over the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778, further in view of Fujimori *et al.*, U.S. Patent No. 5,294,458 (herein referenced as "Fujimori").

GROUND 5.

Claims 1 and 9 have been finally rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as having been obvious in view of Meyer, EP 0,259,713 (herein referenced as "Meyer").

GROUND 6.

Claims 3 – 5, 11, and 12 have been finally rejected under 35 U.S.C. § 103(a) as having been obvious in view of Meyer.

GROUND 7.

Claim 6 has been finally rejected under 35 U.S.C. § 103(a) as having been obvious over Meyer in view of Gil.

GROUND 8.

Claim 10 has been finally rejected under 35 U.S.C. § 103(a) as having been obvious over Meyer in view of Fujimori.

ARGUMENTS

Applicant appeals the Grounds of Rejection, as follows:

GROUND 1 (ANTICIPATION REJECTION ONLY).

The Examiner has finally rejected Claims 1 and 3 – 5 under 35 U.S.C. § 102(b) as anticipated by the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778.

Consistent with guidance from the Decision on Appeal by the Board of Patent Appeals and Interferences in co-pending U.S. Patent Application Serial No. 09/163,778, Applicant respectfully asserts that independent Claim 1 of the present invention recites methods of providing nutrition to

a critical care animal comprising administration of an *artificially produced* canine milk having the recited elements, thereby limiting the claim from a perspective of patentability to those compositions which are indeed *artificially produced* canine milk substitutes. As such, the rejected claims, all of which ultimately depend from Claim 1, cannot be anticipated by Applicant's own disclosures regarding the compositional make-up of *natural* beagle milk. The Examiner's rejection of Claims 1 and 3 – 5 on the basis of 35 U.S.C. § 102(b) therefore cannot be based on natural beagle milk as disclosed by Applicant. The Examiner should be directed to withdraw this rejection.

GROUND 1 (OBVIOUSNESS REJECTION) AND GROUND 2.

The Examiner has rejected Claims 1 and 3 – 5 (***Ground 1***) and Claims 7 – 9, 11 and 12 (***Ground 2***) under 35 U.S.C. § 103(a) as having been obvious in view of the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778.

Claims 1 and 3 – 5 and Claims 7 – 9, 11 and 12 would not have been obvious in view of administration of natural beagle milk. As has been stated in the present specification, commercial canine milk replacers have been previously formulated based upon limited research data. Due to such limited research data, those which are ordinarily skilled in the art have previously been unable to successfully formulate a milk replacer which meets the nutritional needs of the suckling puppy. As such, natural beagle milk, the contents of which having been previously unknown, could not have obviated the rejected claims. Rather, but for Applicant's independent research leading to the present invention, the contents of such milk may have still been unknown. Respectfully, therefore, it is impermissible hindsight to argue that administration of a natural beagle milk could obviate administration of an artificially produced canine milk replacer, particularly since the natural beagle milk had not previously been thoroughly characterized.

The art cited in Applicant's information disclosure statement for this patent application is illustrative to this point. If it would have been obvious formulate a milk replacer based on natural milk, why would the prior art have deviated from what Applicant has characterized and developed? Indeed, one of ordinary skill would not have been motivated to arrive at the present invention, given the previously unknown characteristics of natural beagle milk. As a result of

extensive effort and experience, Applicant has now disclosed *pages* of characterization of various nutrient other other material profiles related to natural canine milk. This was not information that had been available in the public domain, nor would such information have been obvious to any person of ordinary skill.

Moreover, what canine milk would one of ordinary skill have used to base a commercial canine milk substitute which would have been administered to a critical care animal? As described in Applicant's specification, milk composition changes throughout the course of lactation. It would not have been obvious to select a specific canine milk, selected from a specific period of lactation, upon which to conduct research. Again, to state otherwise would be impermissible use of hindsight in view of Applicant's own disclosure as set forth in the present specification. *See* Specification, page 5, lines 14 – 31.

The Examiner's rejection of Claims 1 and 3 – 5 (***Ground 1***) and Claims 7 – 9, 11 and 12 (***Ground 2***) on the basis of 35 U.S.C. § 103(a) is flawed. The Examiner should be directed to withdraw this rejection.

GROUND 3.

The Examiner has finally rejected Claim 6 under 35 U.S.C. § 103(a) as having been obvious over the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778, further in view of Gil *et al.*, U.S. Patent No. 5,709,888 (herein referenced as "Gil").

The method of Claim 6 recites sources of fat selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof. For the same reasons that Claims 1, 3 – 5, 7 – 9, 11, and 12 would not have been obvious in view of the present inventor's own disclosures regarding natural beagle milk, Claim 6 would not have been obvious. Moreover, Gil fails to remedy the deficiencies of the inventor's disclosures regarding natural beagle milk.

As has been stated above, the present invention - - directed to administration of an *artificial* canine milk - - could not have been obviated by Applicant's own disclosures regarding natural

beagle milk, particularly since the natural beagle milk had not previously been thoroughly characterized prior to the present inventor's own research and disclosure in the present patent application.

Moreover, Gil fails to remedy the Examiner's flawed analysis, as Gil fails to disclose or even suggest any canine milk at all, whether a natural canine milk or an artificial canine milk; as such, Gil does not fill any gap in known research that the present inventor filled on his own through diligent research. Even further, Gil is directed to fat mixtures for human nutrition, and models the recited fat mixtures "on the fat content of human milk for infant diets and on the Mediterranean diet for adult nutritional products." *See* Gil, abstract. There is absolutely no disclosure, connection, or even suggestion in Gil to substitute any of the fat mixtures described therein into an artificial canine milk substitute.

Indeed, to do so would be analogous choosing to feeding a human infant - - a baby - - a milk substitute formulated specifically for the needs of a critical care dog rather than one formulated for the specific nutritional needs of the human infant. This is, of course, a rather ridiculous proposition.

The Examiner should therefore be directed to withdraw the rejection of Claim 6 based on Applicant's disclosures regarding natural beagle milk, in view of Gil. Respectfully, the Examiner is using impermissible hindsight, and further constructing obviousness arguments in view of any related known components in any composition known to be useful for a milk composition (even outside the field of critical care canine nutrition).

GROUND 4.

The Examiner has finally rejected Claim 10 under 35 U.S.C. § 103(a) as having been obvious over the present inventor's own disclosures regarding natural beagle milk in priority U.S. Patent Application Serial No. 09/163,778, further in view of further in view of Fujimori *et al.*, U.S. Patent No. 5,294,458 (herein referenced as "Fujimori").

As has been stated above, the present invention - - directed to administration of an *artificial* canine milk - - could not have been obviated by Applicant's own disclosures regarding natural beagle milk, particularly since the natural beagle milk had not previously been thoroughly characterized prior to the present inventor's own research and disclosure in the present patent application.

Moreover, respectfully, it is difficult to comprehend this rejection since the rejection is based on the argument that it would have been obvious to formulate a canine milk substitute by mimicking natural beagle milk (which argument assumes, improperly, that the formula of natural beagle milk would have been readily known or determined), yet the combination of Fujimori would have actually resulted in a substitute that is not similar to natural beagle milk at all due to the use of fructooligosaccharide (FOS) which is not detected in natural beagle milk pursuant to Applicant's research. Moreover, Fujimori does not even disclose a canine milk substitute (natural or artificial), but is rather directed to the use of FOS in pet foods for adult cats and dogs. The Examiner should therefore be directed to withdraw the rejection of Claim 10 based on Applicant's disclosures regarding natural beagle milk, in view of Fujimori.

GROUND 5 (ANTICIPATION ONLY).

The Examiner has finally rejected Claims 1 and 9 under 35 U.S.C. § 102(b) as anticipated by Meyer, EP 0,259,713 (herein referenced as "Meyer"). For the convenience of the Board, a translation of Meyer is attached hereto as the "Meyer Translation Appendix."

Assuming *arguendo* that the Examiner's rejection has followed comments of the Board of Patent Appeals and Interferences in co-pending U.S. Patent Application Serial No. 09/163,778, Applicant will address the comments of the Board in that case. In particular, the Board has noted that page 6, line 36 of the Meyer Reference (from the untranslated document) discloses a composition having a ratio of albumin and globulin to casein of 2.1 to 3.0 : 4.1 to 5.0. Based on this, the Board concludes that "at its range endpoint (casein:whey 5.0:2.1) the ratio is equal to about 70:30." However, Applicant respectfully asserts that this is an improper conclusion. Rather, as illustrated by the enclosed excerpt of Encyclopedia of Food Science, Food Technology and Nutrition, Vol. 7, Eds. Macrae *et al.*, 1993 (particularly, page 4888) (excerpt enclosed for the convenience of the Board as the "Encyclopedia Appendix"), sweet whey and acid whey have a crude protein content of 12.9% and 11.7%, respectively.[1] As such, it cannot be deduced, that two proteins present in whey can together amount to a total whey content. Therefore, Applicant asserts that page 6, line 36 of Meyer does not disclose a casein to whey ratio of about 70:30.

[1] Applicant utilizes this encylopaedic reference merely to provide perspective regarding an illustrative characterization of whey (*i.e.*, that whey is not 100% albumin and globulin). Applicant does not intend to limit whey only to the characterization provided in this particular reference.

Applicant has clearly demonstrated a different approach relative to Meyer, and Claims 1 and 9 are not anticipated in view of this reference. The Examiner should be directed to withdraw this rejection.

GROUND 5 (OBVIOUSNESS REJECTION) AND GROUND 6.

The Examiner has finally rejected Claims 1 and 9 and Claims 3 – 5, 11, and 12 under 35 U.S.C. § 103(a) as having been obvious in view of Meyer.

The Examiner has failed to provide any rationale for this rejection. Indeed, Examples 1 – 4 of Meyer are actually antithetical to obviousness of the present invention as claimed:

Example 1 of Meyer indicates a ratio of casein to whey of about 0.75: 1 (22.5:30);

Example 2 of Meyer indicates a ratio of casein to whey of about 1:1 (30:30);

Example 3 of Meyer indicates a ratio of casein to whey of about 0.7:1 (20:30); and

Example 4 indicates a ratio of casein to whey of about 0.7:1 (20:30).

None of these disclosed relative levels of casein and whey are at all suggestive of the use of artificially produced canine milk substitute comprising casein and whey at a weight ratio of 70:30, as has been presently claimed. The Examiner should be directed to withdraw this rejection.

GROUND 7.

The Examiner has finally rejected Claim 6 under 35 U.S.C. § 103(a) as having been obvious over Meyer in view of Gil. Notably, the Examiner has not provided any rationale for the combination of these references, nor has the Examiner constructed an argument in view of this specific combination, as is seen from the Office Actions dated October 31, 2003 and March 24, 2004.

As stated above with respect to Grounds 5 and 6, Meyer fails to disclose or even suggest use artificially produced canine milk substitutes comprising casein and whey at a weight ratio of 70:30. Moreover, Gil fails to remedy this deficiency; again, Gil relates to fat mixtures for human nutrition, and models the recited fat mixtures "on the fat content of human milk for infant diets

and on the Mediterranean diet for adult nutritional products." *See* Gil, abstract. There is absolutely no disclosure, connection, or even suggestion in Gil to substitute any of the fat mixtures described therein into an artificial canine milk substitute, nor is there any disclosure, connection, or even suggestion to modify the casein and whey ratios set forth in Meyer. The rejection is flawed and the Examiner should be directed to withdraw this rejection.

GROUND 8.

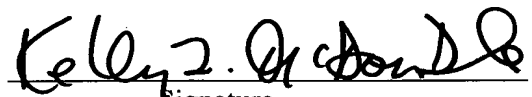
The Examiner has finally rejected Claim 10 under 35 U.S.C. § 103(a) as having been obvious over Meyer in view of Fujimori. Notably, the Examiner has not provided any rationale for the combination of these references, nor has the Examiner constructed an argument in view of this specific combination, as is seen from the Office Actions dated October 31, 2003 and March 24, 2004.

As stated above with respect to Grounds 5 and 6, Meyer fails to disclose or even suggest use artificially produced canine milk substitutes comprising casein and whey at a weight ratio of 70:30. Moreover, Fujimori fails to remedy this deficiency. Fujimori does not even disclose a canine milk substitute (natural or artificial), or even any composition containing casein or whey, but is rather directed to the use of FOS in pet foods for adult cats and dogs. As such, Fujimori fails to suggest any modification of the casein and whey ratios set forth in Meyer, and further fails to suggest inclusion of fructooligosaccharide specifically in an artificially produced canine milk substitue. The Examiner should therefore be directed to withdraw the rejection of Claim 10 based on Meyer in view of Fujimori.

SUMMARY

In view of all of the above, Applicant respectfully requests the Board of Patent Appeals and Interferences to direct the Examiner to withdraw the rejections of Claims 1 and 3 - 12 and allow these claims as patentable subject matter.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY



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December 20, 2004
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CLAIMS APPENDIX

1. (*REJECTED*) A method for providing nutrition to a critical care canine comprising:

administering to said canine an amount of an artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates; wherein said protein comprises casein and whey in a weight ratio of about 70:30.

2. (*CANCELED*).

3. (*REJECTED*) The method of claim 1 in which said composition comprises about 38% protein.

4. (*REJECTED*) The method of claim 1 in which said composition comprises about 28% fat.

5. (*REJECTED*) The method of claim 1 in which said composition comprises about 19% carbohydrates.

6. (*REJECTED*) The method of claim 1 in which the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

7. (*REJECTED*) The method of claim 1 in which said composition contains fatty acids expressed as a percentage of total fatty acids on a dry matter basis, of from 15 to 19% palmitic acid, from about 5 to 9% stearic acid, from about 34 to 38% oleic acid, from about 17 to 21% linoleic acid, from about 1 to 4% a-linoleic acid, from about 0.5 to 2% arachidonic acid, from about 0.2 to 1% docosahexaenoic acid (DHA), from about

2 to 5% Omega-3 fatty acids, from about 18 to 22% Omega-6 fatty acids, and from about 1 to 4% trans fatty acids.

8. (*REJECTED*) The method of claim 1 in which said composition contains amino acids expressed as a percentage of total essential amino acids on a dry matter basis of from about 6 to 10% arginine, from about 4 to 8% histidine, from about 8 to 12% isoleucine, from about 16 to 20% leucine, from about 13 o 17% lysine, from about 2 to 7% methionine, from about 6 to 10% phenylalanine, from about 8 to 12% threonine, from about 1 to 4% tryptophan, from about 9 to 13% valine, from about 2 to 5% cystine, and from about 2 to 6% tryrosine.

9. (*REJECTED*) The method of claim 1 in which said composition ~~of claim 1~~ contains from about 4 to 8% by weight lactose.

10. (*REJECTED*) The method of claim 1 in which said composition contains about 0.50% by weight fructooligosaccharide.

11. (*REJECTED*) The method of claim 1 in which said composition contains from about 27 to 37% by weight fatty acids.

12. (*REJECTED*) The method of claim 1 in which said composition contains from about 15to 25% by weight essential amino acids.

13. (*CANCELED*).

14. (*CANCELED*).

15. (*CANCELED*).

16. (*CANCELED*).

17. (*CANCELED*).

18. (*CANCELED*).

19. (*CANCELED*).

20. (*CANCELED*).

21. (*CANCELED*).

22. (*CANCELED*).

23. (*CANCELED*).

24. (*CANCELED*).

25. (*CANCELED*).

26. (*CANCELED*).

27. (*CANCELED*).

28. (*CANCELED*).

29. (*CANCELED*).

30. (*CANCELED*).

31. (*CANCELED*).

32. (*CANCELED*).

33. (*CANCELED*).

34. (*CANCELED*).

35. (*CANCELED*).

36. (*CANCELED*).

RELATED PROCEEDINGS APPENDIX

The Decision on Appeal by the Board of Patent Appeals and Interferences in related, co-pending U.S. Patent Application Serial No. 09/163,778, to which the present patent application claims priority, is provided on the following twenty-four (24) pages.

P-116

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALLAN LEPINE

Appeal No. 2001-2463
Application No. 09/163,778

ON BRIEF

Before GARRIS, PAWLIKOWSKI and MOORE, *Administrative Patent Judges.*

MOORE, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 and 3-14. Claim 2 has been canceled. Thus, claims 1 and 3-14 are before us on appeal.

REPRESENTATIVE CLAIMS

Claims 1, 13, and 14 are representative of the claimed subject matter and read as follow:

1. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates; wherein said protein comprises casein and whey in a weight ratio of about 70:30.

D. 07/11/03

13. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% by weight carbohydrates, said composition further comprising from about 4 to 8% by weight lactose and about 0.50% by weight fructooligosaccharide.

14. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates, wherein the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

The References

In rejecting the claims under 35 U.S.C. § 103(a), the examiner relies upon the following references:

Kinumaki et al. (Kinumaki)	4,294,856	Oct. 13, 1981
Traitler et al. (Traitler)	4,938,984	Jul. 03, 1990
Fujimori	5,294,458	Mar. 15, 1994
Gil et al. (Gil)	5,709,888	Jan. 20, 1998

Oftedal, "Lactation in the Dog: Milk Composition and Intake by Puppies," J. Nutr., 114:803-812 (1984).

We discuss the following additional reference in the body of this opinion:

Meyer (European Patent)	EP 0 259 713 B1	Mar. 18, 1992

We rely upon the following prior art in formulating the new ground of rejection:

Specification, page 1, lines 8-11, discussing naturally occurring canine milk and the known formulation of replacement milk; page 4, line 11 - page 6, line 22, discussing the detailed analysis of naturally occurring canine milk; and page 7, lines 17-22, discussing the known benefits of fructooligosaccharide (Admitted Prior Art).

The Invention

The invention relates to a canine milk substitute which has been formulated to contain amounts of protein, fat and carbohydrates which closely match the concentration of those components in natural canine milk. The composition includes, by weight of dry matter, from about 35 to 45% protein, from about 25 to 35% by weight fat, and from about 10 to 25% by weight carbohydrates. The protein source comprises casein and whey in a weight ratio of about 70:30. The canine milk substitute is said to provide greater daily weight gain and improved growth in puppies when compared to commercially available milk replacers (Appeal Brief, page 2, lines 10-20). Further details of the claimed invention are seen by reference to claims 1, 13 and 14 reproduced above.

Discussion

I. Prefatory Issues

We preliminarily note that the statement of the rejection in the Examiner's Answer is defective. It states "[c]laims 1 and 3-14 [are] rejected under 35 U.S.C. 103. This rejection is set forth in prior Office Action, Paper No. 9." (Examiner's Answer, page 3, lines 13-14). Paper #9, the Final Rejection, applies 5 separate rejections, none of which is equivalent to the summary statement of the rejections in the Examiner's Answer. Further, no

explanation of the rejection is found there. Instead, a further reference to an unidentified "previous Office Action" is made. (Paper #9, page 2, line 4 - page 3, line 10).

Searching yet further into the prosecution history reveals that the "previous Office Action" must be paper #5, dated December 28, 1999. In that Official Action, each rejection is reiterated "for the reasons stated in the first Office Action" (Paper #5, page 2, lines 14-15) or "for the reasons noted in the first Office Action" (page 3, lines 8-9).

Note MPEP 1.193, which provides in pertinent part:

> If there is a complete and thorough development of the issues at the time of final rejection, it is possible to save time in preparing the examiner's answer required by 37 CFR 1.193 by taking any of the following steps:
>
> > (A) Examiners may incorporate in the answer their statement of the grounds of rejection merely by reference to the final rejection (or a single other action on which it is based, MPEP § 706.07). Only those statements of grounds of rejection appearing in a single prior action may be incorporated by reference. **An examiner's answer should not refer, either directly or indirectly, to more than one prior Office action.** Statements of grounds of rejection appearing in actions other than the aforementioned single prior action should be quoted in the answer. The page and paragraph of the final action or other single prior action which it is desired to incorporate by reference should be explicitly identified (Emphasis Added).

We believe failure to follow this rule has, at least in part, led to the reversal of the applied rejections as the examiner has

failed to address claim 1 as amended to incorporate the subject matter of claim 2. However, for the sake of judicial economy and to speed the decisional process we shall address the rejections.

The rejections at issue, having been exhumed from the prosecution history (Paper #3), are as follows:

A) Claims 1, 3-5 and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal.[1]

C) Claims 6 and 14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade as applied to claims 1, 3-5 and 9, and further in view of Gil.

D) Claims 7 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kakade, Oftedal, and Gil as applied to claims 6 and 14, further in view of Traitler.

E) Claims 8 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claims 1, 3-5 and 9, and further in view of Kinumaki.

F) Claims 10 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claims 1, 3-5 and 9, further in view of Fujimori.

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1 We note that the rejection we have termed ''B'' indicated that Claim 2 was rejected under 35 U.S.C. §103(a) as being unpatentable over Oftedal and Kakade as applied to claims 1, 3-5 and 9, further in view of Irvine. Claim 2 was canceled and incorporated into claim 1, and this rejection was withdrawn. The reference cited in rejection ''B'' was not reapplied.

II. The Claimed Subject Matter

An analysis of the issues necessarily starts with identification of the claimed subject matter, as this determination governs the remainder of the decisional process. We note that all of the appealed claims relate to a composition containing various substituents. The preambles of the appealed independent claims each recite that the composition is "An artificially produced canine milk substitute composition comprising...." (See, e.g. claims 1, 13, and 14.). The claims then go on to recite the actual composition constituents and amounts.

Generally, the preamble does not limit the claims. DeGeorge v. Bernier, 768 F.2d 1318, 1322 n.3, 226 USPQ 758, 764 n.3 (Fed. Cir. 1985). However, the preamble may be limiting "when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). If the preamble is "necessary to give life, meaning and vitality" to the claim, then the claim preamble should be construed as limiting. Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 480-81 (CCPA 1951). This is determined "on the facts of each case in view of the claimed invention as a whole." In re Stencel, 828 F.2d 751, 754, 4 USPQ2d

1071, 1073 (Fed. Cir. 1987); see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1572-73, 40 USPQ2d 1481, 1488 (Fed. Cir. 1996) ("Whether a preamble stating the purpose and context of the invention constitutes a limitation . . . is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.").

In the present instance, the claims are directed to a clearly defined composition, with components and amounts. The preamble adds nothing to the composition other than to state an intended use of the composition. We note that it has been held that a process of use limitation, as recited in the preamble of the claim, has no significance in a product claim. Cf. In re Wiggins, 397 F.2d 356, 359 n.4, 158 USPQ 199, 201-202 n. 4 (CCPA 1968). In Wiggins, the claim was directed to a composition, and the court noted that a composition would not appear to be different in any material manner from the composition of appellants' claims no matter to what ultimate use it would be put.

Accordingly, we find that, on the facts of this case, e.g. the completeness of the formulation of the composition contained in the claims, and the mere statement of use in the preamble, that the preambles of claims 1, 13, and 14 are non-limiting. With this determination in mind, we turn to a discussion of the rejections.

III. The Rejections

A) The Rejection of Claims 1, 3-5 and 9 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal.

The examiner has found that Kakade teaches a milk replacer which comprises protein, fat, carbohydrates, lactose and whey. On a dry matter basis, the examiner has found that the amount of protein can be from 13.3% to 32%; 1.33 -50% oil fat; and 13-90% carbohydrates (by dry matter weight). Lactose can be present from 10-35% of the carbohydrate. The examiner has additionally found that Oftedal teaches protein is present in canine milk in an amount of between 35-45% on a dry matter basis. The examiner thus concludes that it would have been obvious to one of ordinary skill in the art to develop a canine milk with a protein range of 35-45%, as natural milk contains protein levels in that range. Additionally, the examiner concludes that it would have been obvious to optimize the percentages of fat, protein, and carbohydrates (Paper #3, page 2, line 13 - page 4, line 2).

The appellant urges that there is no motivation or reasoning for one to modify the references to meet the claimed limitations, that the references are not directed to compositions which are intended to duplicate canine milk, and that therefore there is no

prima facie case of obviousness. (Appeal Brief, page 5, lines 6-12).

In order to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. See In re Dance, 160 F.3d 1339, 1343, 48 USPQ2D 1635, 1637 (Fed. Cir. 1998); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617.

In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. See WMS Gaming, Inc. v. International Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) (and cases cited therein).

In the present instance, the instant claims broadly claim a canine milk replacing composition having various constituents of fat, protein, and carbohydrate, with a particular protein ratio. The primary references, Oftedal and Kakade, relate to milk and/or milk replacers for animals. Their principal disclosure includes the analysis and/or replacement of natural milk as a source of nutrients. As noted by Kakade, 10-45% carbohydrate is provided in the concentrate, with 10-35% of the concentrate being lactose. (Kakade, column 2, lines 25-30). At least 60% of the 10-16% protein in the concentrate is whey (Id., column 2, lines 36-40). Finally, fat is to be present in an amount of from 1-25% in the concentrate. (Id., column 2, lines 59-61). It is also taught that the food should provide desired growth factors (Id., column 1, lines 34-36).

Oftedal, on the other hand, illustrates that natural canine milk contains about from 39-45% fat, 30-35% protein, and 14-19% carbohydrates.[2]

We find that these references are closely related to the claimed subject matter, the nutrition of suckling puppies. Thus they are reasonably pertinent and would commend themselves to the

2 Calculated from Oftedal's Table 1, page 805.

attention of one of ordinary skill in the art concerned with feeding suckling puppies. We therefore agree with the examiner that these references are properly combinable. Further, we concur that it would have been obvious to one of ordinary skill in the art to optimize the claimed ranges of fat, protein, and carbohydrate as taught by Oftedal to be provided in nature.

The appellant, however, raises a compelling point. The ratio of casein to whey is nowhere found in either reference, and Kakade in fact teaches that the majority of the proteins should be whey (Appeal Brief, page 8, lines 11-15). The examiner has stated it would have been obvious to optimize to the needs of a young animal to adjust the amount of whey and casein. (Examiner's Answer, page 9, lines 3-9). While this statement may be generally true, there is simply no evidence in the cited references of record before us pertaining to this rejection to support the examiner's position.

The only evidence that different proteins can be used is a contrary teaching of 60% whey. We therefore must reverse the rejection of claim 1 over the applied references, as the examiner has failed to establish that this claimed element would have been obvious in view of the cited references utilized in the rejection of claim 1.

C) The Rejection of Claims 6 and 14 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade as applied to claims 1, 3-5 and 9, and further in view of Gil.

As we have reversed the underlying rejection over Oftedal in view of Kakade, we reverse this rejection for the same reasons as noted above.

D) The Rejection of Claims 7 and 11 under 35 U.S.C. §103(a) as being unpatentable over Kakade, Oftedal, and Gil as applied to claims 6 and 14, further in view of Traitler.

As we have reversed the underlying rejection over Oftedal in view of Kakade, we reverse this rejection for the same reasons as noted above.

E) The Rejection of Claims 8 and 12 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claims 1, 3-5 and 9, and further in view of Kinumaki.

As we have reversed the underlying rejection over Oftedal in view of Kakade, we reverse this rejection for the same reasons as noted above.

F) The Rejection of Claims 10 and 13 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claims 1, 3-5 and 9, further in view of Fujimori.

As we have reversed the underlying rejection over Oftedal in view of Kakade, we reverse this rejection for the same reasons as noted above.

IV. New Grounds of Rejection

G) Claims 1, 3-5, 7-9, and 11-12 are rejected under 35 U.S.C. §102(b) as anticipated and alternatively under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art.

The appellant admits in the specification that naturally occurring beagle milk contains various components, including 40.40% protein, 31.8% Fat, 18.5% carbohydrate, and a casein/whey ratio of 70:30 (Specification, page 5, lines 21-26). The specification also admits that it is "generally accepted that milk from the lactating mother provides optimal nutrition to the suckling puppy. Accordingly, milk replacers currently in use have been formulated with the intent of matching the nutrient composition of bitch milk." (Id., page 1, lines 8-11).

Naturally occurring canine milk contains all of the elements of instant claim 1. As we have found the claim preamble to be non-limiting, we therefore conclude that naturally occurring canine milk[3] clearly anticipates the subject matter of claim 1.

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3 We take judicial notice of the fact that the beagle has been nursing puppies with naturally produced beagle milk long before the subject matter of the instant application was invented. For completeness sake, in support of this taking notice we note that the Specification, page 5, footnote, refers to and

In the alternative, given the known desired formulation of milk replacers to closely match the nutrient composition of canine milk, it would have been obvious to one of ordinary skill in the art to formulate a milk replacer with the composition of claim 1 to match the components of the natural beagle milk.

Claims 3-5 are similarly clearly anticipated and/or obvious within the meaning of 35 U.S.C. § 102(b) and/or 103(a) as follows.

Instant claim 3 recites "about 38% protein." Natural beagle milk contains 40.40% protein (specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 38%" protein. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 38% protein, as it was known to formulate milk replacers to match the content of natural milk.

Instant claim 4 recites "about 28% fat." Natural beagle milk contains 31.8% fat (specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 28%" fat. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 28% fat, as it was known to formulate milk replacers to match the content of natural milk.

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utilizes data from a reference work (Lonnerdal) reciting beagle milk composition, and dated 1981 and Oftedal, dated 1984.

Instant claim 5 recites "about 19% carbohydrates." Natural beagle milk contains 18.5% carbohydrates (specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 19%" carbohydrates. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 19% carbohydrates, as it was known to formulate milk replacers to match the content of natural milk.

H. Claims 7, 8, 9, 11, and 12 are rejected under 35 U.S.C. §103(b) as obvious over the Admitted Prior Art.

Instant claim 7 recites 15-19% palmitic acid, about 5-9% stearic acid, about 34-38% oleic acid, about 17-21% linoleic acid, 1-4% alpha-linoleic acid, about 0.5-2% arachidonic acid, about 0.2 to 1% docosahexaenoic acid, about 2 to 5% Omega 3 fatty acids, about 18-22% Omega 6 fatty acids, and from about 1-4% trans fatty acids.

Instant claim 8 recites about 6-10% arginine, 4-8% histidine, 8-12% isoleucine, 16-20% leucine, about 13-17% lysine, about 2-7% methionine, about 6-10% phenylalanine, about 8-12% threonine, about 1-4% tryptophan, about 9-13% valine, about 2-5% cystine, and about 2-6% tyrosine, based on the total weight of amino acids.

Instant claim 9 recites from about 4 to 8% by weight lactose.

Instant claim 11 recites about 27% to 37% by weight fatty acids.

Instant claim 12 recites from about 15 to 15% by weight essential amino acids.

Although the claimed ranges are not specifically exemplified or analyzed for in the Admitted Prior Art beagle milk, the compositions of the claimed milk replacer and the prior art beagle milk are so close (and stated to be modeled upon natural beagle milk) that they are reasonably expected to behave in the same or similar manner. Compare Titanium Metals Corp. v. Banner, 778 F.2d 775, 783, 227 USPQ 773, 779 (Fed. Cir. 1985).

Where general conditions of the appealed claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation, and appellant has the burden of proving any criticality. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-19 (CCPA 1980); In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The appellant has not done so with the claimed compositions vis-a-vis natural beagle milk.

I. Claims 6 and 14 are rejected under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art in view of Gil.

Instant claim 6 recites that the source of fat is corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

Instant claim 14 recites that the composition contains about 35-45% protein, about 25-35% fat, and from about 10-25%

carbohydrates, and the fat source is corn oil, canola oil, butter oil, arachidonic acid, docohexaenoic acid, and blends thereof.

The admitted prior art is as discussed above. Gil teaches a preferred source of fat for a human milk replacer includes an oil such as corn oil (column 10, line 64). Gil also experimentally teaches feeding weanling rats (column 24, line 59 et seq.) from its example 13. Example 13 and example 4a contain the same fat mixtures, and example 4a is said to contain arachidonic and docosahexaenoic acid, with beneficial effect on the rats. (column 17, lines 40-58).

Consequently, it would have been obvious to utilize corn oil, arachidonic acid, or docohexaenoci acid as a fat source in the instantly claimed canine milk replacer of claims 6 and 14 to obtain the beneficial effects found in humans and rats.

J. Claims 10 and 13 are rejected under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art with or without Fujimori.

Claim 10 recites that the composition contains about 0.50% by weight fructooligosaccharide.

Claim 13 recites that the composition contains about 35-45% protein, about 25-35% fat, and from about 10-25% carbohydrates, further containing about 4-8% by weight lactose and 0.5% by weight fructooligosaccharide (FOS).

The Admitted Prior Art is as discussed above. The Admitted Prior Art (specification, page 7, lines 16-22) further states that 0.50% FOS is known to improve the intestinal health of "many animals". Accordingly, it would have been obvious to incorporate the FOS into the claimed composition.

Alternatively, Fujimori teaches that fructooligosaccharides known to be in pet foods to reduce objectionable odors in pet wastes. (See, e.g. Fujimori, column 2, lines 45 et seq.). The lactosucrose is utilized in an amount of 0.25 parts by weight (column 6, lines 25-26). Accordingly, it would have been obvious to use the fructooligosaccharide in the canine milk replacer to obtain the known benefits.

V. Additional Issues

If further prosecution is undertaken, the examiner and appellant should obtain a complete translation of the Meyer reference. We note that the Search Report from the EPO designates Meyer an "X" reference. We have reviewed the record and observe that Meyer was submitted and reviewed as an English language abstract only. Although the examiner appears to have initialed the PTO 1449 (Paper #6) supplied by the appellant, in the absence of a German language translation, we do not see how it is possible for such review to have occurred.

It appears that at least instant claims 1, 3, 4, 5, and 9 should be rejected under 35 U.S.C. §103(a) as being unpatentable over Meyer. Meyer recites in its disclosed claim 1 (taken from the translated, published claims which were not previously provided to the PTO) a canine milk substitute which includes (by weight) a protein content of more than 30%, a fat content of more than 25%, and a lactose (a carbohydrate) content of less than 30% (Meyer, page 6, lines 29-36).

The protein is divided between albumin and globulin (components of whey) and casein at a ratio of 2.1 to 3.0:4.1 to 5.0. (Id., page 6, line 36). At its range endpoint (casein:whey 5.0:2.1) the ratio is equal to about 70:30. We observe that each of these disclosed limitations in the claim of Meyer overlaps the claimed ranges of claim 1.

A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. See, e.g., In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974). In cases involving overlapping ranges, our reviewing court and its predecessor have consistently held that even a slight overlap in range establishes a prima facie case of obviousness. Woodruff,

919 F.2d at 1578, 16 USPQ2d at 1936-37 (concluding that a claimed invention was rendered obvious by a prior art reference whose disclosed range ("about 1-5%" carbon monoxide) abutted the claimed range ("more than 5% to about 25%" carbon monoxide).

Claim 3 recites that the protein content is "about 38%." Meyer's claimed range discloses a protein content of more than 30%, which encompasses the instantly claimed range of about 38%.

Claim 4 recites that the fat content is "about 28%." Meyer's claimed range is more than 25%, which encompasses the instantly claimed range of about 28%.

Claim 5 recites that the carbohydrate content is "about 19%." Meyer's claimed range of lactose (a carbohydrate) is less than 30%, which encompasses the instantly claimed range of about 19%.

Claim 9 recites that the composition contains from "about 4 to 8% by weight lactose." Meyers disclosed claimed range of lactose is less than 30%, which encompasses the instantly claimed range of about 4 to 8%.

Thus, it appears that Meyer may render the above-discussed claims obvious. Accordingly, in the event of further prosecution, a complete translation of Meyer should be obtained and considered against all of the claims of this application.

Summary of Decision

The rejection of Claims 1, 3-5 and 9 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal is reversed.

The rejection of claims 6 and 14 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade as applied to claims 1, 3-5 and 9, and further in view of Gil, is reversed.

The rejection of claims 7 and 11 under 35 U.S.C. §103(a) as being unpatentable over Kakade, Oftedal, and Gil as applied to claims 6 and 14, further in view of Traitler is reversed.

The rejection of claims 8 and 12 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claim 1, 3-5 and 9, and further in view of Kinumaki is reversed.

The rejection of claims 10 and 13 under 35 U.S.C. §103(a) as being unpatentable over Kakade and Oftedal as applied to claim 1, 3-5 and 9, further in view of Fujimori, is reversed.

The following new grounds of rejection are made:

Claims 1, 3-5, 7-9, and 11-12 are rejected under 35 U.S.C. §102(b) as anticipated and alternatively under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art.

Claims 7, 8, 9, 11, and 12 are rejected under 35 U.S.C. §103(b) as obvious over the Admitted Prior Art.

Claims 6 and 14 are rejected under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art in view of Gil.

Claims 10 and 13 are rejected under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art with or without Fujimori.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 1.196(b)

BRADLEY R. GARRIS)
Administrative Patent Judge)
)
)
BEVERLY A. PAWLIKOWSKI) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
JAMES T. MOORE)
Administrative Patent Judge)

JM/ki

Appeal No. 2001-2463
Application No. 09/163,778

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MEYER TRANSLATION APPENDIX

A translation of Meyer, EP 0,259,713, relevant to Ground 5 – 8, is provided on the following nine (9) pages.

EP 0,259,713 B1

EUROPEAN PATENT OFFICE
PATENT NO. 0,259,713 B1

Int. Cl.[5]:	A 23 K 1/18 A 23 K 1/08 A 23 K 1/16 A 23 C 11/04
Filing No.:	87,112,501.9
Filing Date:	August 27, 1987
Publication Date:	March 18, 1992
Laid-open Date:	March 16, 1988 Patent Bulletin 88/11
Granting Date:	March 18, 1992 Patent Bulletin 92/12
Priority Date: Country: No.:	 September 1, 1986 Germany 3629710
Designated Contracting States:	Austria, Belgium, France, Germany, Great Britain, Italy, Liechtenstein, Netherlands, Switzerland

SYNTHETIC FEED MILK SUBSTITUTE, IN PARTICULAR MILK FOR DOGS

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Documents Cited:

EP-A-0 185 142
DE-A-2 655 380
DE-A-3 039 352
DE-A-3 512 705
FR-A-1 551 098
EP-A-0 241 097
DE-A-2 831 951
DE-A-3 327 963
DE-B-1 219 318
Lebensmittellexikon [Food Lexicon]
Page 561 VEB

Note: Opposition against the granted European patent may be filed with the European Patent Office by anyone within nine months after publication of the notification of the grant of the European patent. Opposition must be filed in writing and reasons must be stated. It is considered filed only once the opposition fee has been paid (Art. 99(1) European Patent Convention).

Description

The subject matter of the present invention relates to a synthetic feed milk substitute, in particular milk for dogs, according to the precharacterizing clause of Claim 1.

Synthetic feed milk substitutes, in particular milks for dogs, are well-known and are based primarily on dry milk or whey powder, milk proteins, fats, and half-finished products in the form of vitamins, minerals, trace elements and the like.

All of the known milks for dogs are marked by an excessively high milk powder or whey powder fraction, ranging overall from more than 60% up to a maximum of 85%. Such milks for dogs which, as a rule, are altered calf's milks, have considerable disadvantages if they are used as the exclusive feed for whelps. It was found that when whelps are fed with this type of milk for dogs they sometimes suffer from life-threatening diarrhea and, moreover, that these milks have too low a nutrient value for use in feeding whelps.

For this reason, in cases where the dogs are raised without the mother animal, they must be fed the known milks for dogs many times, such as approximately every two hours, throughout the day and night, which is hardly practicable.

DE-B-1 219 318 describes a filter [sic; feed] milk substitute for dogs which consists of cow's milk and additives and which is as close as possible to the composition of natural dog's milk.

Thus, the problem to be solved by the present invention is to make available a synthetic feed milk substitute on the basis of cow's milk for raising carnivorous animals, in particular a milk for dogs, which is suitable for use as an exclusive feed for young animals and thus can be practially used to raise the animals without the mother animal.

This problem is solved according to the present invention by the features contained in the characterizing clause of Claim 1.

As provided by a first embodiment of the present invention, the milk powder fraction of the feed is considerably reduced, i.e., to a fraction of less than 60 wt% and especially less than 45 wt%. The resulting deficit is made up by other milk proteins which are additionally added, i.e., by milk proteins with a low lactose content but an extremely high raw protein content. This measure takes into consideration the fact that the disadvantage of the milks for dogs known so far was primarily attributable to the high lactose content which, in turn, is attributable to the high fraction of skim milk powder and/or whey powder in the synthetic feed milk substitute. According to a second embodiment, milk powder is not used at all and, instead, a completely desweetened milk and/or whey protein powder is used as the basis of the feed. These protein concentrates in the form of a powder can be manufactured by means of ultrafiltration and similar processes. This makes it possible to considerably minimize the lactose content of the feed, i.e., of the milk for dogs. Yet another embodiment provides for a reduction of the milk powder in combination with a completely desweetened milk and/or whey protein powder.

As provided by the present invention, the lactose fraction of the product can be reduced to less than 30% and preferably to 1 to 25%. At the same time, the raw protein content can be increased to more than 30% and preferably to 31 to 40%. As a result of the reduction of the fraction of skim milk powder, the skim milk functions and is used mainly as the carrier of fat, while the lactose fraction is controlled by the appropriate addition of milk proteins.

The milk proteins used are preferably whey proteins that are obtained by means of ultrafiltration, in particular soluble nondenatured proteins comprising the fractions
beta-lactoglobulin
alpha-lactalbumin
serum albumin
immunoglobulins
protease-peptone fraction.

During the ultrafiltration, the whey is turbulently passed over the surface of membranes. Through the action of a hydrostatic pressure, water, lactose, salts and low-molecular substances

permeate [through the membranes] while the high-molecular substances, such as the whey proteins, are retained. Thus, it is mainly the lactose that is removed so that broken-down protein fractions obtained from milk protein are added to make up for the reduced fraction of skim milk powder. For this, whey proteins with 1 to 10% of lactose, preferably whey proteins with up to 1% of lactose, are used. In addition, milk proteins in the form of caseins are added, in particular sodium, potassium, calcium caseins or acid caseins. These are best obtained by means of precipitation from skim milk with acids, washing, mechanical separation and special drying. It is also possible to use rennet casein which is obtained by means of enzymatic precipitation from skim milk, washing, mechanical separation and special drying.

The advantage of the measures according to the present invention is to be seen in the fact that as a result of the use of these milk proteins, the reduction of the lactose fraction of the synthetic feed aimed at is achieved while at the same time only milk proteins are used.

According to the present invention, the albumin-globulin ratio relative to the casein fraction is accurately adjusted from 2.1 to 3.0:4.1 to 5.0.

To compensate for potential natural variations in the raw protein component, it is useful to add pure amino acids. Especially suitable for this purpose are methionine, lysine and cystine, preferably in quantities of up to 2% of the overall formulation. It is especially useful to adjust the ratio of lysine to methionine to approximately 3.1%:1.65%.

The raw fat content of the synthetic milk is preferably higher than 25%, and especially preferred is a content of 25.5 to 40%.

Preferably, short-chain fatty acids, from C-12 on, and only small fractions of long chain fatty acids with C-20 and higher (less than 0.5%) are used.

An especially preferred fatty acid distribution is obtained as follows:

C-12	0.1 to 0.5 parts by weight
C-14	2.0 to 10.0 parts by weight
C-16	20.0 to 41.0 parts by weight
C-16/1	1.3 to 6.0 parts by weight
CC-18	2.4 to 29.0 parts by weight
C-18/1	25.0 to 48.0 parts by weight
C-18/2	2.5 to 15.0 parts by weight
C-18/3	0.2 to 3.0 parts by weight
C-29/0	and higher at most 1 part by weight (sum total of 100 parts by weight).

In addition, it is also useful to add an emulsifying agent and an antioxidant to the fat composition. For this purpose, the conventional emulsifying agents can be used as emulsifiers, such as fatty acid monoglyceride diglycerides, esters of fatty acid monoglycerides, sugar fatty

acid esters, native or modified lecithin or mixtures thereof. Antioxidants to be used for this purpose can also be chosen from those conventionally used, such as ethoxyquine and/or BHT.

Examples of the fat fraction of the synthetic feed milk follow from the table below:

	All values in %							
Fat formula	1	2	3	4	5	6	7	8
Beef tallow	30	80	-	90	75	50	-	-
Soybean oil	10	18	5	8	20	20	10	18
Lard	-	-	20	-	3	18	-	-
Sunflower oil	5	-	10	-	-	-	-	-
Bone grease	53	-	60	-	-	-	88	70
Emulsifier + Antioxidant	2	2	5	2	2	2	2	2
Total	100%							

Preferred fatty acids are myristic acid, palmitic acid, palmitolic acid, stearic acid, oleic acid, linoleic acid and linolenic acid.

To improve the tolerability of the synthetic milk for dogs, lactobacilli are added, preferably lactobacillus acidophilus and lactobacillus bifidus, in a quantity of 10^6 bacilli per 100 g of milk or 0.05-1% dry feed relative to the overall formulation.

Other additives are pectins or tannins in a quantity of 0.001 to 0.5%.

Below, examples of the feed according to the present invention will be described:

Example 1

30% Skim milk powder
30% Fat
20% Whey protein with 1% lactose fraction
15% Caseins
5% Half-finished products (consisting of vitamins, minerals, trace elements, addition of amino acids).

This formulation has a lactose fraction of 15.8%, a raw protein fraction of 39% and a fraction of raw fat of 30%.

Example 2

40% Skim milk powder
35% Fat

10% Whey protein
10% Caseins
5% Half-finished products

The formulation has a lactose content of 21%, a content of raw protein of 30.5%, and a raw fat fraction of 35.5%.

Example 3

41% Skim milk powder
27% Raw fat
16% Whey protein
11% Caseins
5% Half-finished products

This preferred formulation has a lactose fraction of 21.2% and a raw protein fraction of 36.2%.

In the examples given, the biological valence of the raw protein component is on the average 92 and the PER value is 3.2.

Example 4

31.0% Whey protein powder
33% Raw fat
21.8% Casein
7.0% Raw ash
0.1% Raw fibers
1.35% Methionine
1.2% Calcium
0.9% Phosphorus
3.0% Lysine
13.2% Albumin

and vitamin A (25,000 IU), vitamin E (200 mg) and vitamin D3 (3,000 IU) as well as residues and trace elements.

This formulation has a raw protein fraction of 36.5% and a lactose fraction of less than 4%. The nutrient value is approximately 7,200 kcal or 30,300 kJ.

Example 5

30.0% Dry milk powder
31.3% Fat

20.7% Casein
7,4% Raw ash
1.31% Methionine
1.34% Calcium
0.86% Phosphorus
3.02% Lysine
10.5% Albumin
and the following vitamins: vitamin A (25,000 IU), vitamin E (200 mg), and vitamin D_3 (3,000 IU) as well as residues and trace elements.

This formulation has a raw protein fraction of 33.3% and a lactose fraction of 17.3%. The nutrient value is approximately 6,500 kcal or 27,300 kJ.

Example 6

30% completely desweetened milk protein
25% completely desweetened whey protein
32.5% mixture of fats
2.5% emulsifying agent
10% half-finished products

The formulation according to the present invention is notable for the fact that it is as close as possible to the milk of the mother animal, thus making it possible to raise animals largely without the mother animal with the synthetic feed, and by an extremely simple production. The feed is marked by a very high nutrient value, i.e., approximately 30,000 kJ per kg of dry substance, which means that a complete caloric substitute for the mother's milk is ensured. Whelps now need to be fed only three to four times per day, starting on the first day of life. Accurately maintaining the content of essential amino acids and protein components and matching the fatty acid pattern to that of the mother's milk as much as possible further ensures that the milk can be used to raise carnivorous animals, in particular dogs and cats, without the mother animals.

The percentage values used refer to percent by weight.

Claims

1. A synthetic feed milk substitute on a cow's milk basis for rearing carnivorous animals, especially dogs, containing fat and half-finished products in the form of vitamins, mineral substances, trace elements and/or amino acid additives and the like, said synthetic feed milk substitute being produced on a skim milk basis using milk powder and/or fully desweetened milk protein or whey protein powder,
characterized by
a milk powder content of less than 45 percent by weight, a lactose content of less than 30 percent by weight, a fat content of more than 25 percent by weight and a protein content of more than 30 percent by weight with a content ratio of albumin and globulin to casein of 2.1 to 3.0 : 4.1 to 5.0.

2. A feed according to claim 1,
characterized in that
the milk is composed exclusively on the basis of desweetened milk protein and/or whey protein powder, of which a content of up to 60%, preferably up to 55%, is used.

3. A feed according to claim 1,
characterized by
a skim milk powder content of 30 to 41 percent by weight.

4. A feed according to claim 3,
characterized in that,
apart from skim milk powder, milk protein with a content of 15 to 55 percent by weight, preferably 20 to 45 percent by weight, is contained.

5. A feed according to any of the preceding claims,
characterized in that
the milk proteins are whey proteins obtained by way of an ultrafiltration process as well as caseins.

6. A feed according to claim 5,
characterized in that
the content of the milk proteins added amounts to 10 to 40%, preferably 15 to 25%.

7. A feed according to claim 6,
characterized in that
the whey proteins are soluble, non-denatured proteins consisting of
beta lactoglobulin
alpha lactalbumin
serum albumin
immunoglobulins
protease-peptone-fraction.

8. A feed according to claim 5,
characterized in that
the casein content is 5 to 30 percent by weight, preferably 10 to 15 percent by weight.

9. A feed according to claim 8,
characterized in that
sodium, potassium, calcium or acid caseins are used as caseins.

10. A feed according to any of the preceding claims,
characterized in that
it contains pure amino acids for balancing variations in the crude protein component.

11. A feed according to claim 10,
characterized in that
it contains methionine, lysine and cystine as pure amino acids in amounts of up to 2% percent, respectively.

12. A feed according to claim 11,
characterized in that
the content ratio of lysine : methionine is about 3.1% : 1.85%, relative to the dry mass.

13. A feed according to any of the preceding claims,
characterized in that
the crude fat content is 25.5 to 40 percent by weight.

14. A feed according to any of the preceding claims,
characterized by
an addition of bacterial strains, preferably lactobacilli or streptococcus species.

15. A feed according to any of the preceding claims,
characterized by
an addition of pectins or tannin in an amount of 0.001 to 1.5 percent by weight.

ENCYCLOPEDIA APPENDIX

An excerpt from Encyclopedia of Food Science, Food Technology and Nutrition, Vol. 7, Eds. Macrae *et al.*, 1993, relevant to Ground 5 – 8, is provided on the following ten (10) pages.

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WHEY AND WHEY POWDERS

Contents

Production and Uses

Origins and Characteristics of Liquid Whey

Whey, the by-product of casein and cheese manufacture, was for many years treated as a waste product. Disposal was by either feeding to animals, or running to waste in streams or on to the land. In the past few decades, however, environmental pressures coupled with a recognition of the inherent value of whey solids have resulted in the development of processes for the conversion of liquid whey into a range of valuable food ingredients. This article will review the source of wheys, compositional factors affecting utilization, alternatives for processing of whey, properties of whey powders and their uses in the food industry. *See* Casein and Caseinates, Uses in the Food Industry; Cheeses, Chemistry of Curd Manufacture

Source and Composition of Wheys

Whey may be considered as the watery substance remaining after coagulation of the casein in milk, either through the addition of acid (as in casein manufacture), or through the action of a protease such as chymosin (as in cheese manufacture). Clearly, the composition of whey will vary considerably, depending on the source of the milk and the manufacturing process involved. However, on average, whey contains about 65 g per kilogram of solids, comprising about 50 g of lactose, 6 g of protein, 6 g of ash, 2 g of nonprotein nitrogen and 0·5 g of fat. Casein wheys generally have a significantly higher level of ash than cheese wheys.

It is convenient to class whey into three major groups:

- Sweet wheys: titratable acidity 0·10–0·2%, pH typically 5·8–6·6. This category would include wheys produced from chymosin-coagulated cheeses with low levels of acidity.
- Medium acid wheys: titratable acidity 0·20–0·40%, pH typically 5·0–5·8. This class could include whey from the manufacture of fresh acid cheese such as ricotta or cottage cheeses. *See* Cheeses, Soft and Special Varieties
- Acid wheys: titratable acidity greater than 0·40%, pH less than 5·0. This class would include casein wheys made by addition of mineral acids, and some fresh acid cheese wheys.

A detailed composition of dried sweet and acid wheys is shown in Table 1.

The following points are of particular relevance in assessing options available for the processing of whey streams:

(1) Whey has a total solids of about 6·5%, i.e. it is a fairly dilute product. Thus, to produce 1 kg of whey powder requires the removal of about twice as much water as does the production of 1 kg of milk powder. Water removal is a costly unit operation, and this factor alone mitigates against many options for whey processing.

(2) Of the total solids in whey, more than 75% is lactose. The effective utilization of whey is therefore inextricably linked with the effective utilization of lactose. Unfortunately, lactose is not a commercially valu-

Table 1. Composition of sweet and acid whey powders, and whey protein concentrates

	Composition (%)					
	Moisture	Crude protein	True protein	Lactose	Fat	Ash
Sweet whey[a]	3·2	12·9	—	74·4	1·1	8·4
Acid whey[a]	3·5	11·7	—	73·4	0·5	10·8
35% WPC[b]	4·6	36·2	29·7	46·5	2·1	7·8
50% WPC[b]	4·3	52·1	40·9	30·9	3·7	6·4
65% WPC[b]	4·2	63·0	59·4	21·1	5·6	3·9
80% WPC[b]	4·0	81·0	75·0	3·5	7·2	3·1

[a] Data from Posati LP and Orr ML (1976) *Agriculture Handbook*, No. 8-1. Washington: US Department of Agriculture.
[b] Data from Glover FA (1985) *Ultrafiltration and Reverse Osmosis for the Dairy Industry. Technical Bulletin*, No. 5. Reading: National Institute for Research In Dairying.

Table 2. Relative sweetness and solubility of lactose, sucrose and some monosaccharides

Sugar	Relative sweetness[a]	Solubility (g per 100 g solution)[b] 10°C	30°C	50°C
Sucrose	100	66	69	73
Lactose	16	13	20	30
D-Galactose	32	28	36	47
D-Glucose	74	40	54	70
D-Fructose	173	—	82	87

[a] Data from Pazur JH (1970). Oligosaccharides. In: Pigman W, Horton D and Herp A (eds) *The Carbohydrates: Chemistry and Biochemistry*, p 69. New York: Academic Press.
[b] Data from Shah NO and Nickerson TA (1978) Functional properties of hydrolyzed lactose: solubility, viscosity and humectant properties. *Journal of Food Science* 43: 1081.

able sugar, as it is not particularly soluble, nor is it particularly sweet (Table 2). These factors limit the commercial applications of whey solids very considerably. *See* Lactose

(3) The proteins present in whey comprise about 50% β-lactoglobulin, 25% α-lactalbumin and 25% other proteins. Whey proteins have a very high nutritional profile, are high in essential amino acids, and can have excellent functional properties. Clearly, therefore, the whey proteins are the most valuable components of whey, and most whey-processing operations (e.g. ultrafiltration, manufacture of lactalbumin) therefore aim at increasing the proportion of whey proteins in the end-product. *See* Protein, Quality

(4) The mineral content and low pH of casein wheys severely limit their commercial exploitation. The vast majority of whey-based products are commercially manufactured from low or medium acid wheys.

(5) Whey has a very large biochemical oxygen demand (BOD), which poses major difficulties for its disposal. It should be also noted that a number of options for whey processing, particularly those which result in an increase in the proportion of protein in the product, also result in the production of a waste product which contains most of the lactose originally present. This stream in turn will require further processing. Thus, the problems posed by the BOD of the original whey are therefore often little affected by many of the whey-processing options.

Processing Options

Processing options for whey fall into four main areas:

- those concerned with simple removal of water (spray or roller drying to yield whey powder);
- those concerned with increasing the ratio of protein in the end-product (ultrafiltration for the manufacture of whey protein concentrates, fractionation processes for the manufacture of protein isolates, heat treatment for the production of lactalbumin); *See* Filtration of Liquids
- those concerned with utilization of the lactose in whey (treatment with lactase or heat/acid for lactose-hydrolysed products, fermentation to a range of products such as lactic acid, citric acid and single-cell protein);
- those designed to alter the mineral composition of the product (electrodialysis and ion exchange for the manufacture of demineralized products).

Each of these is considered in turn below.

Drying of Whey

Spray drying of whey is a fairly straightforward operation, with conditions employed similar to those applying for the spray drying of milk. Thus, the whey is concentrated to 40–70% total solids and spray (or roller) dried to a moisture content of less than 5%. The drying of whey is, however, complicated by its high lactose content. Lactose exists in two isomeric forms, α-lactose and β-lactose. α-Lactose crystallizes as a hydrate, whereas solid β-lactose contains no water of crystallization. However, when solutions of whey are dried rapidly, there may be insufficient time for the crystallization of α-lactose to the monohydrate, and it forms as amorphous α-lactose. The dry lactose in the whey product is then essentially in the same form as in the liquid. Neither α-lactose hydrate nor β-lactose is hygroscopic. However, amorphous α-lactose is highly hygroscopic, and will absorb moisture from the air, resulting in a hydrate which occupies more space than the amorphous form. This effect causes the commonly observed lumping and caking in many whey powders. *See* Drying, Spray Drying

Both hygroscopic and non-hygroscopic whey powders are manufactured. The former are produced by simple drying of the whey concentrate. The manufacture of non-hygroscopic whey powders relies on the conversion of much of the lactose in the liquid concentrate to a crystalline form prior to drying. This is achieved by holding the concentrate under appropriate conditions to allow for extensive formation of α-hydrate crystals. Alternatively, a process similar to instantizing may be used, in which the surface of the partly dried whey powder particles are partially humidified prior to completion of the drying operation. This stage permits additional crystallization of the α-lactose during drying.

Means for Increasing the Protein Content of the End-product

Whey solids contain about 11% protein. Many of the most popular methods of whey treatment aim at increasing this level, with end-products containing between 35% and virtually 100% protein. It should be noted that each of these methodologies results in a waste stream high in lactose, which will pose separate utilization or disposal problems.

Ultrafiltration

Ultrafiltration is the most common method used by the dairy industry to produce a range of whey products with increased protein content, known as whey protein concentrates (WPCs). Ultrafiltration relies on the passage of whey near a membrane with a pore size such that low-molecular-weight materials such as lactose and ash pass through the membrane, whereas higher-molecular-weight components such as proteins are retained. On ultrafiltration of whey, therefore, the solids content of the product retained by the ultrafiltration membrane (the retentate) is higher in protein and lower in lactose than the original whey, and the solids content of the product which passes through the membrane (the permeate) is high in lactose and ash and has minimal protein content.

WPCs are produced from a wide range of wheys, generally to protein contents of 35%, 50% and 75% (Table 1). WPC of 35% protein content is often used as a skim milk powder replacer in applications where the specific functionality of skim milk powder is not important (WPC of 35% protein content is generally significantly less expensive than skim milk powder). WPC of 50% protein content is not widely manufactured, and generally is used for specific applications only. WPC of 75% protein content can have very desirable functional properties, and these can be readily manipulated by modification of the manufacturing process. Such products often have excellent water-binding, gelation and emulsifying properties, making them sought after as functional ingredients by the food industry. ***See*** Emulsifiers, Organic Emulsifiers

Lactalbumin Production

Whey proteins are heat-sensitive, and can be precipitated by heat treatment under appropriate conditions of pH and ionic strength. This property is utilized in the manufacture of lactalbumin. (Note that lactalbumin – the product of heat precipitation of the proteins from whey – contains a mixture of denatured α-lactalbumin, β-lactoglobulin and other whey proteins. 'Lactalbumin' should not be confused with α-lactalbumin.) In the manufacture of lactalbumin, whey is heated to denature, coagulate and precipitate the whey proteins; the sediment is recovered by settling and decantation (or centrifugation), washed to remove excess salt, and the product recovered by centrifugation or filtration prior to drying, grinding and bagging. The heat treatment used in the manufacture of lactalbumin results in extensive denaturation of the whey proteins, resulting in a product of poor functionality. Lactalbumin, therefore, finds its best applications in products where protein fortification is necessary, but it is not required to provide any functional properties.

Protein Isolation and Fractionation

In contrast to the precipitation of whey proteins by heat treatment in the manufacture of lactalbumin, protein isolation and fractionation methodologies aim at separation of the proteins from whey in such a form that they remain as far as possible fully undenatured, and thus retain their functionality. These products (protein concentrates and isolates) are therefore high in protein content, and can have exceptional functional properties of considerable value to the food industry.

Protein concentrates contain the whey proteins in about the same proportions as that in whey. (Note that in this article, the term 'protein concentrates' is used for high-protein products containing the individual whey proteins in about the same ratio as that present in whey, the term 'whey protein concentrate' is used for such products manufactured by ultrafiltration, and the terms 'protein isolates' and 'protein fractions' are used to refer to high-protein products with a higher ratio of a particular protein than that present in whey.) Such protein concentrates are generally manufactured by the use of a nonspecific absorbent to bind the proteins in whey, followed by elution of the proteins by treatment of the absorbent with a specific eluent. Absorbents which have been commercially used include carboxymethylcellulose and a range of mineral oxides. Although these absorbents are comparatively nonspecific, they can show preference for binding particular proteins under set conditions of pH, temperature and ionic strength. Thus, these processes can be used to produce protein isolates, for example with a higher ratio of β-lactoglobulin to α-lactalbumin than that present in whey.

Protein fractionation technology is also developing which relies on separation of α-lactalbumin from β-lactoglobulin on the basis of their differing solubilities under specified conditions of pH, temperature and ionic strength. It is therefore possible, for example, to separate by sedimentation most of the α-lactalbumin from whey by careful manipulation of processing conditions. Both the α-lactalbumin which has sedimented, and the residual soluble protein (mostly β-lactoglobulin) are comparatively undenatured, and thus retain their high

functionality. The conditions employed in these processes are very mild, and do not result in any denaturation of the whey proteins. With such processes it is therefore possible to produce isolates high in β-lactoglobulin (with extremely high gel strength) and α-lactalbumin (a product which may have considerable potential in nonallergenic infant foods).

Lactose Processing Options

The options for treatment of whey involving lactose may be divided into three groups – those involving a fermentation step, those involving separation of the lactose and its utilization, and those involving enzymatic hydrolysis of the lactose to produce galactose and glucose. *See* Galactose

Fermentation

There are many options for the fermentation of whey described in the literature, including the production of biogas, biomass, alcohol, lactic acid and citric acid. However, the dairy industry worldwide has not taken up such opportunities to any great extent. Plants do exist for the processing of whey into biomass and alcohol, notably in the USA and New Zealand (alcohol), but the throughput of these units is comparatively small.

Separation of Lactose

In many respects this is a most attractive option, as it can be used also as a process for the treatment of waste streams from other whey treatment operations such as ultrafiltration. However, as indicated above, lactose is not a commercially desirable product, and the market for lactose is comparatively inelastic. Manufacture of lactose (normally α-lactose hydrate) generally involves protein removal, concentration, refiltration, further concentration, induction of crystallization, and separation of crystals with a basket centrifuge.

Lactose Hydrolysis

The hydrolysis of lactose yields the sweet soluble sugars glucose and galactose, thus increasing the applications of the product. Such hydrolysis can be carried out by treatment of whey with lactase, or by treatment of deproteinized whey at elevated temperatures and low pH. It should be noted that it is difficult to dry hydrolysed wheys because of the tendency of the monosaccharides formed by the hydrolysis to produce glasses on the surface of the drier.

Changes in Mineral Composition

The mineral composition of whey, particularly casein wheys, is such that it deleteriously influences the taste and applications of the product. Whole or partial demineralization of whey is therefore a popular option with manufacturers. In general, this is accomplished by treatment of whey by ion exchange (no preferential removal of ions), or electrodialysis (preferential removal of monovalent ions). Both processes are expensive and produce high levels of intractable effluents.

More recently, an option for demineralization using 'open' reverse-osmosis membranes has been developed. These membranes allow the passage of ions and water, whilst retaining all other whey components, including lactose.

Applications

Whey solids may be used as a food ingredient in products such as calf milk replacers, infant formulae, whey cheese, beverages, baked goods, ice cream and other dairy products, comminuted meat products and imitation milk products. In most cases, the whey solids contribute little to the functionality of the product, offering only a comparatively low-cost source of protein, carbohydrate and calcium.

Similarly, lactalbumin is used in foods where protein fortification is required, but additional functionality is not essential. Lactalbumin is commonly used in products such as baked goods and comminuted meat products.

WPCs are used where both protein fortification and functionality is required, although WPC of 35% protein content is generally employed directly as a cost-effective skim milk powder replacer. WPC of 75% protein content, with its excellent gelation properties, is often used as a cost-effective egg white replacer.

The main market for demineralized wheys is in the formulation of cow's milk-based infant formulae with a closer composition to that of human milk. Demineralized wheys also may be used effectively as beverage ingredients, where the saltiness of the undemineralized product might normally preclude its use. *See* Infant Foods, Milk Formulas

Lactose is used in sauces, instant drinks and meat products, where its low sweetness and ability to enhance flavour are advantages. Lactose is also used extensively in the confectionery and baked goods industries. Highly purified lactose is also used in the pharmaceutical industry for tablet making, and as a substrate for the manufacture of penicillin and other fermented products.

Applications of hydrolysed wheys include ingredients in foodstuffs such as beverages, and other products such as moist animal foods, where it can be used as a humectant to replace the more expensive glucose commonly used.

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Table 1. Average composition of warm skim milk protein

	g per 100 g milk	Total protein content (%)
Colloidal casein	2·36	74
Serum casein	0·26	8
β-Lactoglobulin	0·29	9
α-Lactalbumin	0·13	4
Bovine serum albumin	0·03	1
Total immunoglobulins	0·06	2
Other proteins	0·06	2

Data from Farrell Jr HM and Thompson MP (1974) *Physical equilibria in milk: proteins*. In: Webb BH, Johnson AH and Alford JA (eds) *Fundamentals of Dairy Chemistry*, p. 465. Westport, CT: AVI Publishing.

Protein Concentrates and Fractions

In the past 20 years, whey processing has been revolutionized by the development of methodologies for the manufacture of highly functional food products containing a higher proportion of protein than that of whey. Such technology generally involves either ultrafiltration, or selective separation of whey proteins (either by adsorption technology, or by utilization of the differing solubility characteristics of whey proteins under specified conditions of pH and temperature). This article will discuss the properties of the major proteins of whey, whey protein products and their methods of manufacture, and the application of such products in the food industry.

Characteristics of Whey Proteins

Whey proteins are those which remain in solution after removal of the caseins from milk, either by treatment with chymosin, or by acidification. The distribution of proteins in skim milk is shown in Table 1. *See* Casein and Caseinates, Methods of Manufacture

β-Lactoglobulin is the major protein in whey, comprising about one-half of the total protein present. It occurs in a number of variants, and has a monomer molecular weight of about 18 000. It should be noted that it is only outside the pH range 3·5–7·5 that β-lactoglobulin exists as a monomer. Inside this range, it generally exists as a dimer although, under certain circumstances, some variants may form an octomer. β-Lactoglobulin is comparatively heat-sensitive and may be denatured by heat treatment much above 60°C.

α-Lactalbumin has a monomer molecular weight of about 14 000, and is somewhat more heat-resistant than is β-lactoglobulin. There are many other serum proteins (including immunoglobulins) in whey, most of which are readily heat denaturable. For example, heat treatment of skim milk at 70°C for 30 min denatures only 6% of the α-lactalbumin, but 32% of the β-lactoglobulin and 89% of the immunoglobulins – cumulatively, such heat treatment results in denaturation of about one-third of the total serum proteins. In whey, heat treatment is often carried at a pH quite removed from that of milk. It should be noted that the pH of heat treatment of whey will have a considerable influence on the magnitude of the degree of denaturation of each of the whey proteins. *See* Heat Treatment, Chemical and Microbiological Changes

As globular proteins, both α-lactalbumin and β-lactoglobulin have the potential to be highly functional food ingredients. Unfortunately, many of the processes employed for whey protein recovery result in their partial denaturation, which generally reduces the functionality of the product.

Major Products and Applications

Whey Protein Concentrates

Whey protein concentrates are manufactured by the ultrafiltration of whey. In this process, whey is passed against a semipermeable membrane, which selectively allows passage of low-molecular-weight materials such as water, ions and lactose, whilst retaining higher molecular weight materials such as protein in the 'retentate'. The retentate is then further concentrated by evaporation, and spray dried to yield whey protein concentrates (WPCs). WPCs are generally available commercially with protein contents of 35, 50 and 75%. For the higher protein products, a process known as

Table 2. Functionality of whey proteins in food

Functional property	Mode of action	Food system
Solubility	Protein solvation	Beverages
Water absorption	Hydrogen bonding of water; entrapment of water	Meat sausages, cakes, breads
Viscosity	Thickening, water binding	Soups, gravies, salad dressing
Gelation	Protein matrix formation and setting	Meats, curds, baked goods, cheese
Cohesion–adhesion	Protein acts as adhesive material	Meat sausages, baked goods, pasta products
Elasticity	Hydrophobic bonding in gluten; disulphide links in gels	Meats, bakery products
Emulsification	Formation and stabilization of fat emulsions	Sausages, salad dressing, coffee whitener, soup, cakes, infant formula
Fat absorption	Binding of free fat	Sausages, doughnuts
Foaming to entrap gas	Forms stable film	Chiffon, desserts, cakes, whipped toppings

Data from Kinsella JE (1976) *Functional properties of proteins in foods: a survey. CRC Critical Reviews in Food Science and Nutrition* 7: 219.

'diafiltration' is employed, in which additional water is added to the retentate during manufacture to 'wash out' more of the low-molecular-weight materials from the retentate.

Whey proteins offer foodstuffs a wide range of potential functionality, as shown in Table 2. A number of factors influence the functional properties of WPCs. These include the source of whey, its protein content, the heat treatment applied to the whey or ultrafiltration retentate during manufacture, and the lipid content and mineral content of the WPCs.

In general, WPCs of lower protein content have more limited functionality than those of higher protein content. In many cases, WPCs serve more than one functional purpose in foods. For example, as whey proteins remain soluble over a wide pH range, and in particular near pH 4·5, they may be used in acidic drinks as protein fortifiers. They may also bring emulsifying properties to these products and, if desired, may also add turbidity. WPCs can be used as water binders in products such as baked goods and processed meats. In such cases, processing temperatures must be sufficiently high to denature the whey proteins, but not so high as to disrupt their water-binding properties. WPCs also can have excellent gelation characteristics, and can assist in the formation of heat-induced gels in meat products and baked goods. The emulsifying properties of WPCs can be employed in products such as salad dressings. WPCs may also have useful foaming properties, producing very stable foams on whipping. *See* Emulsifiers, Organic Emulsifiers; Water, Structure, Properties and Determination

The manufacture of WPCs with such widely varying and yet specific functional properties requires the careful control of manufacturing conditions. Currently, much ultrafiltration processing of whey is carried out on an *ad hoc* basis, with little understanding of the effects of individual processing parameters on the conformation or structure of the individual proteins, or on the functionality of the product. It should also be noted that the functionality of the whey products can be permanently impaired by the use of excessive temperatures or extremes of pH during processing.

Mineral composition is an important factor determining whey protein functionality. Many of the functional properties of WPCs are considerably influenced by either demineralization or by the addition of calcium salts. Clearly, the manufacturing process employed in the whey production process will influence the mineral content of the product, and thus its functionality.

Whey proteins can also be recovered by the application of heat to whey to cause coagulation of the proteins (lactalbumin manufacture), or by adsorption or ion exchange (using adsorbants such as carboxymethylcellulose – such as in the Bi-Pro process, or inorganic oxides – such as 'Spherosil' reagents) or complex formation (with reagents such as polyphosphates). The manufacture of lactalbumin by heat treatment of whey is widespread. Some small-scale plants are commercially manufacturing whey protein isolates utilizing either Spherosil or carboxymethylcellulose. The products of these operations are highly functional, high value-added whey protein fractions which have high specific functionality. However, in general, the commercial application of these processes appears to be limited by the high costs and low protein-binding capacity of the adsorbents.

Whey Fractions

Whey proteins can be recovered as mixtures of the proteins in whey by use of the technologies outlined above. Commercially, ultrafiltration technology is dominant for such processes. However, WPCs manufactured by ultrafiltration have not in general lived up to

their promise of offering reliable highly functional cost-effective ingredients to the food industry. In particular, the functionality of WPCs is often poor and/or highly variable. Further, the functional properties of WPCs are often well below those expected from their protein composition. This may be due to mechanical or heat damage to the proteins during manufacture, or to the presence of other compounds in whey which inhibit the development of full functionality.

To overcome such difficulties, a number of alternative options for whey protein fractionation have been developed. These aim at manufacture of protein fractions containing a higher proportion of a particular protein than that present in whey solids.

Ion Exchange

Ion exchange or adsorption was briefly discussed above as a means for separation of proteins from whey. However, the adsorbents used can also selectively adsorb specific proteins from whey under specified conditions of pH and temperature. For example, under appropriate conditions certain Spherosil adsorbents can selectively remove a significant proportion of the β-lactoglobulin from whey, leaving a fraction rich in α-lactalbumin as the effluent from the adsorption process.

Such processes generally employ batch operation, involving adsorption, elution and regeneration.

Ion Depletion

This technology relies on the fact that β-lactoglobulin is insoluble in solutions of low ionic strength, particularly in the vicinity of its isoelectric point. This principle has been used in a number of studies which have led to pilot scale separation procedures. The products in general were substantially β-lactoglobulin, although other proteins were present. However, the yield of the process was poor, with only about 30% of the protein present in whey recovered as the precipitate.

Thermal Separation

A series of studies have recently shown that the solubility of α-lactalbumin decreases very markedly under certain conditions of pH, temperature (below that of denaturation) and ionic strength. These conditions have no effect on the solubility of β-lactoglobulin. Clearly, this difference in solubility characteristics may be exploited as a means of preparation of whey protein fractions. Two processes based on this principle have reached the stage of near commercialization – one in France, and the other in Australia. The major difference between the two is the starting material – the French process uses untreated whey, the Australian process uses whey concentrated to 12% solids by ultrafiltration. In the Australian process, the pH of the ultrafiltration retentate is adjusted to 4·2, and the process of aggregation initiated by heating of the mixture to 64°C for 5 min. During this process, the α-lactalbumin aggregates into small particles. The product is then diluted with water to assist in formation of larger aggregates, and the sediment (which is mostly α-lactalbumin) separated, for example, by centrifugation or microfiltration. The separated sludge is evaporated and dried, to yield a fraction high in α-lactalbumin (α fraction). The supernatant is subjected to ultrafiltration and diafiltration (to assist in removal of ash and lactose), and dried to yield a fraction high in β-lactoglobulin (β fraction). The α fraction contains about 50% protein (mostly α-lactalbumin) and 40% lactose, and the β fraction contains about 75% protein (mostly β-lactoglobulin) and 15% lactose.

It is probable that the products from the French and Australian processes will be similar in functionality – in each case, the β fraction is low in lipid content. The β fraction has been shown to have excellent gelation characteristics (much greater than those shown by the best 75% WPC). Further, the gel strength exhibited by the β fraction can readily be manipulated by minor modification to processing conditions. Clearly, this product has considerable potential as a highly functional food ingredient, with applications similar to those of egg white.

The α fraction contains most of the lipid and phospholipid in whey, and should be expected to show excellent emulsifying properties. A further application for the α fraction is in 'humanized' infant foods. Although whey-based products are common components of infant foods, whey contains a significant amount of β-lactoglobulin, a protein which has no analogue in human milk. On the other hand, human milk does contain an analogue to bovine α-lactalbumin. Clearly, therefore, infant foods based on (β-lactoglobulin-free) α fraction may offer considerable advantages in reducing allergenic response. *See* Infants, Breast- and Bottle-feeding

Ferric Chloride Fractionation

Techniques have been described in the literature for the treatment of partially demineralized whey with ferric chloride to precipitate β-lactoglobulin selectively as a ferric complex at near neutral pH. By contrast, at an acidic pH, almost all proteins except β-lactoglobulin are preferentially precipitated. In this case, the separated complex can be solubilized by a change in pH to near neutral, and the ferric ion separated by, for example, ultrafiltration. Such processes do not appear to be near commercialization.

Table 3. Some uses of whey proteins and whey protein concentrates in foods

Baked custard	Coffee whitener	Meat analogues
Beverages	Cream filling	Meat extenders
Acid-clear	Cream icings	Meat loaf
Acid-turbid	Cream sauces	Meringues
Neutral	Cream desserts	Noodles
Biscuits	Cultured beverages	Pasta
Breads	Doughnuts	Potato flakes
Cakes	Egg white replacer	Puddings
Cake fillings	Egg yolk replacer	Sauces
Confectionery	Gravies	Sausage
Caramels	Hot dogs	Sherbet
Milk chocolate	Ice cream	Snack foods
Canned beans	Imitation cheese	Tortillas
Cereals	Imitation milk	Whipped toppings
Chocolate drink	Macaroni	Yogurt

Data from Marshall KR and Harper WJ (1987) *Whey Protein Concentrates. Bulletin of the International Dairy Federation*, No. 388B, p 21. Brussels: International Dairy Federation.

Removal of Lipid from Whey and Whey Protein Fractions

The lipid fraction in whey is believed to inhibit much of the potential functionality of WPCs, and whey protein fractions. The lipid fraction in whey is also partly responsible for the fouling of the membranes on ultrafiltration processing of whey. Removal of the lipid fraction can thus improve processing efficiency (if ultrafiltration is employed) as well as product functionality.

Removal of such lipid fractions from whey prior to ultrafiltration or fractionation can be achieved by microfiltration using membranes of an appropriate pore size to remove the comparatively large lipid-containing material. However, fouling of microfiltration membranes (presumably also by the lipid-containing fraction) in such processes has, as yet, mitigated against commercial adoption of this approach. It is likely, however, that improvements in microfiltration membranes coupled with appropriate adjustment of processing conditions will result in commercialization of such processes in the near future.

The addition of calcium to aggregate lipoproteins in whey has also been proposed as an alternative to microfiltration processing. Whilst this process is technically effective, it would pose particular difficulties on scaling up to commercial operation.

A number of the whey fractionation processes previously outlined result in the preferential transfer of any lipid-containing portion of the whey into one particular fraction. For example, the lipid fraction in whey is preferentially found in the α fraction produced by the Australian process utilizing thermal aggregation. Such lipid material may be removed from whey fractions by, for example, microfiltration. This would result in a protein fraction of increased functionality, and a lipid fraction with excellent emulsification characteristics.

Summary of Whey Fractionation Methodologies

Of the various whey fractionation processes outlined, only the procedures based on adsorption/ion exchange involving the use of carboxymethylcellulose and Spherosil are in commercial operation, and these only in comparatively small-scale operations. The thermal procedures for whey fractionation are nearing commercialization. Of the remainder, the use of microfiltration for pretreatment of whey to remove lipid-containing material is likely to become commercial within the next few years. The remainder of the processes outlined seem unlikely to be of commercial interest.

Functionality of Concentrates and Individual Whey Fractions

Of their nature, it is likely that whey protein fractions will have much greater and more reliable functionality than will WPCs, even WPCs of 75% protein content. Although the existing production of whey protein fractions is limited in the main to those from the Bi-Pro and Spherosil processes, and are of comparatively small tonnage, the ongoing development of the thermal aggregation processes will likely see production of whey fractions increase sharply in the next few years. Already whey protein fractions attract much higher returns than WPCs and, with increased production, it is probable that increased applications will be identified, resulting in increased demand. Some products in which WPCs and whey fractions have been commercially utilized are listed in Table 3.

Whey fractions and whey protein concentrates bring many valuable functional properties as food ingredients. They can modify some or all of the organoleptic, visual, hydration, surfactant, structural, textural and rheological properties of the food, resulting in improved consumer acceptance of the product. It is probable that the further development of specialized whey fractions with reliable and well-defined functional properties will see a marked increase in the application of these products over the next few years.

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